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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,206	10/26/2000	Daniel E.H. Afar	G&C 129.21-US-U1	3714

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	27

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/697,206	AFAR ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32 and 44-61* is/are pending in the application.

4a) Of the above claim(s) *46-49,52-55,58-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32,44,45,50,51,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 29-30, 32, 44-45, 50-51, 56-57 are examined in the instant application, wherein claims 29-30, 32, 44-45, 50-51, 56-57 are examined only to the extent of a method for detecting the presence of prostate, colon, breast, lung or bladder cancer, comprising detecting the mRNA level of 20P2H8 gene.

The following are the remaining rejections.

RESTRICTION

Applicant argues that the claims are directed to identifying dysregulated cellular growth or neoplasm, by monitoring specific 20P2H8 gene expression. Applicant asserts that the expression of 20P2H8 gene can be monitored along a well established pathway known to all students in molecular biology, and that although 20P2H8 protein and 20P2H8 mRNA are physically different compositions, they are inexorably tied up in the 20P2H8 gene expression pathway, as defined by Lodish et al, 2000, and indicated in the previously submitted Declaration by Mary Faris. Applicant asserts that the present claims do not require novel methods for monitoring gene expression, and given the information provided in the present specification, it would be equally plausible to monitor 20P2H8 protein and 20P2H8 mRNA in monitoring 20P2H8 gene expression levels, even though such monitoring may involve different method steps. Applicant asserts that such method steps are known in the art, and the present claims are not intended to

distinguish monitoring mRNA levels and protein levels as completely different inventions. Applicant asserts that rather, monitoring 20P2H8 protein and 20P2H8 mRNA are separate embodiments of the presently claimed invention.

Applicant recites the history of the restriction prosecution. Applicant argues that Applicant has not elected detecting levels of mRNA of 20P2H8, as the Office did not mention that claim 30 was also directed to measuring expression of 20P2H8 polynucleotide, i.e. including both mRNA and protein expression. Applicant asserts that claim 30 only existed in group X, and was not split into two or more groups at the time the election was required by the Office.

It is noted that after review and reconsideration, the original claim 30 was found to be inadvertently omitted from group XII in the original restriction requirement of paper No:11, on 12/10/01, and the original claim 30 has been rejoined with group XII, besides belonging to group X, because the original claim 30 reads on a method for identifying neoplasm comprising determining the protein level or mRNA level of 20P2H8 gene expression, and thus encompasses the inventions of both groups X and XII.

It is noted that in the original restriction requirement of paper No:11, on 12/10/01, it was clearly stated that group X is drawn to a method for identifying neoplasm comprising **measuring** the expression of 20P2H8, or **20P2H8 mRNA level.** Thus, even though claim 30 was inadvertently omitted in group X, it is clear that when group X was elected, Applicant elected a method for identifying neoplasm comprising **measuring** the expression of 20P2H8, or **20P2H8 mRNA level**, and **not** a method for identifying neoplasm comprising **measuring 20P2H8 polypeptide level** of group XII.

Applicant's arguments have been considered but are found not to be persuasive for the following reasons:

The recitation of Lodish et al and of the previously submitted Declaration by Mary Faris is acknowledged and entered.

It is noted that monitoring the 20P2H8 protein level and 20P2H8 mRNA level requires different method steps, different reagents used, different dosages, schedules used, response variable and criteria for success. The searches for 20P2H8 protein level and 20P2H8 mRNA level require different searches, which are not co-extensive, because 20P2H8 protein and 20P2H8 mRNA do not share the same structure. Therefore, it would be a serious burden for the Examiner to search both groups X and XII together. Thus monitoring 20P2H8 protein and 20P2H8 mRNA as separate embodiments of the presently claimed invention would constitutes patentably distinct inventions.

The requirement is still deemed proper, and is therefore made **FINAL.**

Accordingly, claims 29-30, 32, 44-45, 50-51, 56-57 are examined in the instant application, wherein claims 29-30, 32, 44-45, 50-51, 56-57 are examined only to the extent of a method for detecting the presence of prostate, colon, breast, lung or bladder cancer, comprising detecting the mRNA level of 20P2H8 gene.

INFORMATION DISCLOSURE STATEMENT

The signed PTO-1449 of paper No:10 is enclosed therewith. It is noted that the PTO-1449 of the information disclosure statement of paper Nos:25-26 is a duplicate of the PTO-1449 of paper No:10.

OBJECTION

The amendment of figure 2 filed on 08/25/03 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows: The added molecular weight standard (under bp symbol) in figure 2 is not found in the original disclosure.

Applicant is required to cancel the new matter in the response to this Office action.

SEQUENCE RULE COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the following reasons:

The nucleotide sequences in the amended figure 2 legend are not accompanied by sequence identification numbers.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Claims 29-30, 32, 44-45, 50-51, 56-57 remain rejected under 35 USC 112, first paragraph for lack of enablement for a method of detecting prostate, colon, breast, lung or bladder cancer for reasons already of record in paper NO:21.

Applicant argues that in figure 2, the cDNA was analyzed by RT-PCR using 25x and 30x amplification and due to the amplification, the results are no longer quantitative, but only qualitative. Applicant argues that the Northern analysis however is a quantitative experiment, and therefore, differential expression is not definitively shown in figure 2, but differential expression is clearly present in the Northern data of figure 3. Applicant asserts that the present data do not indicate a discrepancy in the test results.

Applicant's arguments in paper No:24 have been considered but are found not to be persuasive for the following reasons:

It is noted that in Northern blot, there is **no** expression of mRNA of 20P2H8 gene in normal prostate and bladder tissues. Because of the absence of the expression of mRNA of 20P2H8 gene in normal prostate and bladder tissues as shown by Northern blot, one would expect that there would not be any or there would be very little mRNAs of 20P2H8 gene in normal prostate and bladder tissues, as compared to prostate or bladder cancer tissues, using amplification in a PCR, under the same amplification conditions for both normal and cancer tissues. Thus one would not know which method in the claimed invention is reliable, especially in view that it is well known in the art that PCR is routinely used for detecting differential expression of gene.

REJECTION UNDER 35 USC 102 (a or e)

1. Claims 29-30, 32, 44-45, 50-51, 56-57 remain rejected under 35 USC 102(a) as being anticipated by WO 9938972-A2 for reasons already of record in paper No:21.

Applicant argues that the sequence taught by WO 9938972-A2 spans only 1-599 nucleotides from the total of 3600 base pairs of the claimed sequence, or only 9% of the open reading frame of the claimed gene. Applicant asserts that the present claimed gene would not be detected by the sequence disclosed in WO 9938972-A2.

Applicant's arguments in paper No:24 have been considered but are found not to be persuasive for the following reasons:

It is noted that the claims do not recite any specific probes used for the detection of the claimed sequence of SEQ ID NO:1.

Thus since no specific probe is used in the claimed method, detecting the sequence taught by WO 9938972-A2 in colorectal cancer, breast cancer and lung cancer would also detect the claimed sequence, and thus the method taught by WO 9938972-A2 seems to be the same as the claimed method.

Because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is anticipated because the method will inherently lead to the claimed effects. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

2. Claims 29-30, 32, 44-45, 50-51, 56-57 remain rejected under 35 USC 102(e) as being anticipated by US 6,262,333B1 for reasons already of record in paper No:21.

Applicant argues that the sequence taught by 333' patent spans only nucleotides 1388-1726 from the total of 3600 base pairs of the claimed sequence, or only 21% of the open reading frame of the claimed gene. Applicant asserts that the present claimed gene would not be detected by the sequence disclosed in 333' patent.

Applicant's arguments in paper No:24 have been considered but are found not to be persuasive for the following reasons:

It is noted that the claims do not recite any specific probes used for the detection of the claimed sequence of SEQ ID NO:1.

Thus since no specific probe is used in the claimed method, detecting the sequence taught by 333' patent in cancer would also detect the claimed sequence, and thus the method taught by 333' patent seems to be the same as the claimed method.

Because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is anticipated because the method will inherently lead to the claimed effects. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

November 13, 2003